

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
25 October 2001 (25.10.2001)

PCT

(10) International Publication Number
WO 01/78812 A1

(51) International Patent Classification⁷: **A61M 5/315**

(21) International Application Number: **PCT/DK01/00259**

(22) International Filing Date: **11 April 2001 (11.04.2001)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
PA 2000 00622 **13 April 2000 (13.04.2000)** **DK**

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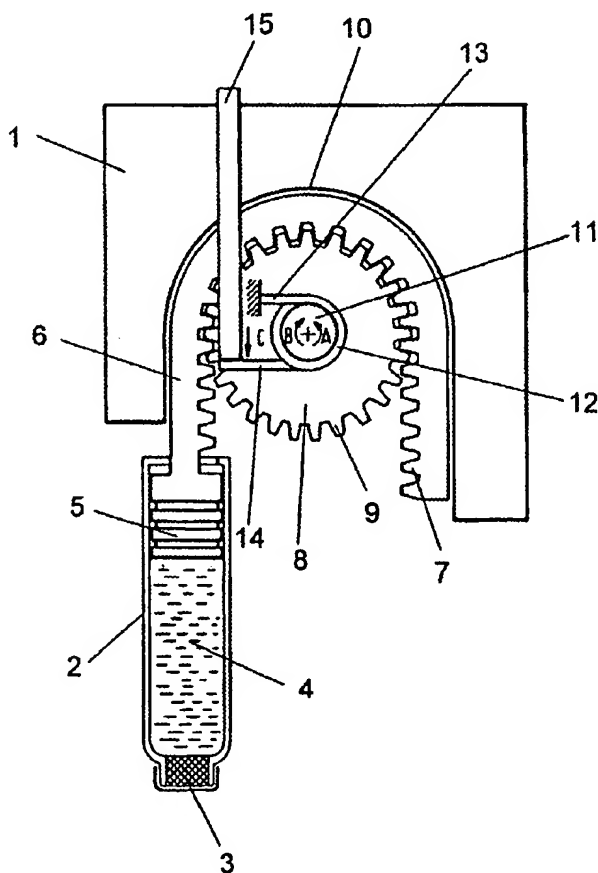
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(81) Designated States (*national*): AE, AG, AL, AM, AT, AT
(utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA,
CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE
(utility model), DK, DK (utility model), DM, DZ, EE, EE
(utility model), ES, FI, FI (utility model), GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK,
SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ,
VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: **A DRUG DELIVERY DEVICE PROVIDED WITH A ONE-WAY MECHANISM**



(57) Abstract: A drug delivery device comprising a housing (1) with a drug container (2) being provided with delivering means comprising a piston (5) for expelling a drug (4) from the drug container (2). The housing (1) further comprising a displaceable piston rod (6) abutting the piston (5) of the drug container (2) and rotating means being in engagement with the piston rod (6), said rotating means being provided with a one-way mechanism. The one-way mechanism comprises a helical spring (12) wound tightly around an axle (11), one end of said helical spring (12) being fixed in relation to the housing (1), the other end of the helical spring (12) being in a free state.



WO 01/78812 A1



(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Published:

— *with international search report*

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A drug delivery device provided with a one-way mechanism

The invention relates to a drug delivery device comprising a housing with a drug container, said drug container having delivering means comprising a piston for expelling a drug from the drug container, said housing further comprising a displaceable piston rod abutting the piston of the drug container, rotating means being in engagement with the piston rod, said rotating means being provided with a one-way mechanism.

The delivery device may be of any type that delivers a liquefied drug to a person as an aerosol spray, an injection or a high-pressure jet. Preferably, however, the delivery device is an injection syringe that may be of a single-use type or a type having an exchangeable drug container or cartridge.

A drug delivery device of this kind is known from US-A-4,367,739 that discloses a syringe provided with a threaded actuating rod with a piston that is arranged in a container or barrel containing the drug. The actuating rod is provided with a knurled knob at the end opposite the piston, said knurled knob being provided with a one-way mechanism. The one-way mechanism comprises a ratchet lock that may be released by manually disengaging a ratchet tooth from a ratchet wheel.

This type of one-way mechanisms is known in a number of appliances where movement in one direction is allowed while movement in an opposite direction is prevented. The movement may be linear or rotating.

Although widely used, manufacturing of a ratchet lock is relatively complicated since it comprises manufacturing of a ratchet tooth part and a ratchet wheel, each having matching teeth, and mounting each of these parts with cooperating parts of the device in which the ratchet lock is to be used. Finally, the cooperating parts are assembled.

It is an object of the present invention to provide a drug delivery device with a rotatable axle provided with a one-way mechanism that is structurally simpler than the previously known one-way mechanisms of the known devices.

This is achieved by providing the drug delivery device mentioned in the opening paragraph with a one-way mechanism that comprises a helical spring wound tightly around said axle, one end of said helical spring being fixed in relation to the housing, the other end of the helical spring being in a free state.

By arranging the one-way mechanism in this way a very simple and yet reliable one-way mechanism is provided. Further, the one-way mechanism is easy to build into a drug delivery device since it comprises very few parts.

The drug delivery device may be of a single-use type or a type having an exchangeable drug container or cartridge. If the drug delivery device is of the latter type, a release button is provided, said release button being able to displace the free end of the helical spring in a direction of unwinding the helical spring. Thereby the helical spring loses its frictional engagement with the axle and the axle is free to rotate in either direction.

In this way the piston rod can be retracted from the cartridge and the cartridge can be exchanged.

In a preferred embodiment the piston rod is provided with a tothing and is in engagement with a piston rod driving wheel provided with a complementary tothing, said piston rod driving wheel being mounted on said axle. In this embodiment, displacement of the piston rod is provided by rotating the axle, said rotation being provided by any known means, e.g. by a push button in engagement with the axle or by an electric motor.

In order to minimize the size of the drug delivery device the piston rod may be flexible and is positioned partly around the piston rod driving wheel. A guiding face may be provided in the housing, said flexible piston rod being positioned between said guiding face and said piston rod driving wheel.

The invention will be described in detail in the following with reference to the drawings in which

Fig. 1 shows a part of drug delivery device comprising a one-way mechanism according to the invention, and

Fig. 2 shows in enlarged scale the working principle of the one-way mechanism.

In Fig. 1 a part of a drug delivery device according to the invention is shown. The drug delivery device comprises a housing 1 provided with an accommodation for an exchangeable drug container or cartridge 2. The cartridge 2 is provided with a rubber seal 3 in a first end thereof, said rubber seal 3 being penetratable by a hol-

low injection needle (not shown) for administration of the drug 4 from the cartridge 2. A displaceable piston 5 is provided in the cartridge 2 for expelling the drug 4.

A flexible piston rod 6 is provided in the housing 1. One end of the flexible piston rod 6 abuts the piston 5 provided in the cartridge 2 and by displacing the flexible piston rod 6 the piston 5 is displaced in the cartridge 2, expelling an amount of the drug 4 from the cartridge 2.

The flexible piston rod 6 is provided with teeth 7 forming a toothing at the inwardly bending side and is in engagement with a piston rod driving wheel 8 provided with teeth 9 that are complementary with the teeth 7. The flexible piston rod 6 is positioned between the piston rod driving wheel 8 and a guiding face 10 of the housing 1.

The piston rod driving wheel 8 is mounted on an axle 11 which is rotatable in an anticlockwise direction (in the direction of the arrow A) as well as in a clockwise direction (in direction of the arrow B).

When the axle 11 is rotated in the direction of the arrow A, the flexible piston rod 6 is displaced downwards in the cartridge 2 displacing the piston 5 and expelling an amount of the drug 4. The axle 11 is rotated in the direction of the arrow A when an amount of the drug 4 is to be administered to a person.

When the axle 11 is rotated in the direction of the arrow B, the flexible piston rod 6 is displaced upwards in the cartridge 2, optionally totally retracted from the car-

tridge 2. The axle 11 is rotated in the direction of the arrow B when the cartridge 2 is to be exchanged which requires that the flexible piston rod 6 is removed from the cartridge 2.

The rotation of the axle 11, which controls the displacement of the flexible piston rod 6, is controlled by any known means and is not shown. For instance, the axle 11 may be rotated by mechanical means, such as a push-button provided with a toothed rack that cooperates with a gear-wheel provided on the axle 11, or it may be rotated by an electric motor. In the drug delivery device the dose to be administered may be preset and administration is achieved either by pressing the push-button or by activating the electric motor whichever is the case.

In a drug delivery device it is important to prevent dose built-up, i.e. to assure that the amount of drug expelled from the cartridge 2 corresponds to the set dose when the axle 11 is rotated a preset rotation. Therefore, it is important that the flexible piston rod 6 in normal use is prevented from being displaced backwards in the cartridge 2. If the flexible piston rod 6 is displaced backwards in the cartridge 2 and no longer abuts the piston 5, the next amount of administered drug will be smaller than prescribed which is undesirable.

In order to prevent the flexible piston rod 6 in being displaced backwards a helical spring 12 is wound tightly around the axle 11. The helical spring 12 has a first end 13 that is fixed to the housing 1 of the drug delivery device and a second end 14 that is in a free state inside the housing 1.

The helical spring 12 is wound tightly around the axle 11 and is therefore frictionally engaged with the axle 11. However, when the axle 11 is rotated anticlockwise in direction of the arrow A, the helical spring 12 loosens due to its free second end 14 and allows the axle 11 to be rotated in this direction.

If it is attempted to rotate the axle 11 clockwise in direction of the arrow B, the helical spring 12 is tightened even more due to the fixed first end 13 and the axle 11 is instantly prevented from being rotated in this direction.

The helical spring 12 being wound tightly around the axle 11 in this way assures that the axle 11 can be rotated in one direction only.

However, when the cartridge 2 is to be exchanged, the flexible piston rod 6 have to be retracted from the cartridge 2, i.e. it has to be drawn backwards by rotating the piston rod driving wheel 8 clockwise. As described above, this rotation is prevented by the helical spring 12 wound around the axle 11. However, by pressing the free end 14 of the helical spring 12 downwards in direction of the arrow C the helical spring 12 loses its frictional engagement with the axle 11 and the axle 11 is allowed to rotate clockwise thereby retracting the flexible piston rod 6 from the cartridge 2. The free end 14 of the helical spring 12 may be pressed downwards by a push-button 15 extending out of the housing 1.

The working principle of the above-described one-way mechanism is shown in Fig. 2 in an enlarged scale. The

axle 11 is rotatable in an anticlockwise direction (arrow A) and in a clockwise direction (arrow B).

A helical spring 12 is wound tightly around the axle 11 thereby being in frictional engagement with the axle 11. A first end 13 of the helical spring 12 is fixed to the housing 1 of the drug delivery device while the other end 14 of the helical spring 12 is in a free state.

Rotation of the axle 11 in the direction of the arrow A is allowed since rotation in this direction loosens the helical spring 12 whereby the frictional engagement between the axle 11 and the helical spring 12 decreases.

Rotation of the axle 11 in the direction of the arrow B, however, is prevented since the frictional forces between the axle 11 and the helical spring 12 is increased instantly due to the ever more tightening of the helical spring 12.

If the free end 14 of the helical spring 12 is displaced in the direction of the arrow C, the helical spring is slightly unwound which causes the frictional engagement between the axle 11 and the helical spring 12 to decrease drastically and allows the axle 11 to be rotated clockwise.

The helical spring 12 is pre-wound before it is positioned on the axle 11. The pre-wound helical spring 12 preferably has an inner diameter that is slightly smaller than the outer diameter of the axle 11 when it is not mounted on the axle 11. When mounting the helical spring 12, it is slightly opened causing the inner diameter to increase to a size larger than the outer diameter of the

axle 11. Then the helical spring 12 is positioned around the axle and released. When mounted, the helical spring 12 is in frictional engagement with the axle 11.

The invention has been described with reference to a preferred embodiment comprising a flexible piston rod 6. However, the invention may also be applied in other drug delivery devices where a rotating one-way mechanism is applicable.

C l a i m s

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1. A drug delivery device comprising a housing (1) with a drug container (2), said drug container (2) having delivering means comprising a piston (5) for expelling a drug (4) from the drug container (2), said housing (1) further comprising a displaceable piston rod (6) abutting the piston (5) of the drug container (2), rotating means being in engagement with the piston rod (6), said rotating means being provided with a one-way mechanism, **characterised** in that the one-way mechanism comprises a helical spring (12) wound tightly around an axle (11), one end of said helical spring (12) being fixed in relation to the housing (1), the other end of the helical spring (12) being in a free state.

2. A drug delivery device according to claim 1 **characterised** in that a release button (15) is provided, said release button (15) being able to displace the free end of the helical spring (12) in a direction of unwinding the helical spring (12).

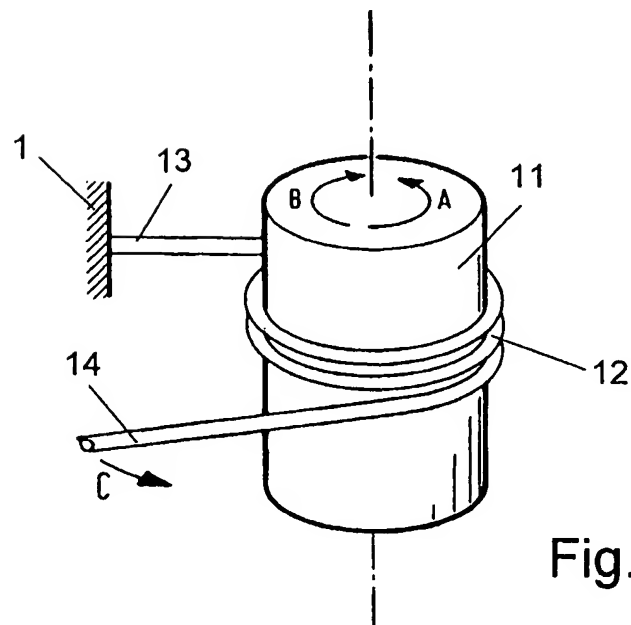
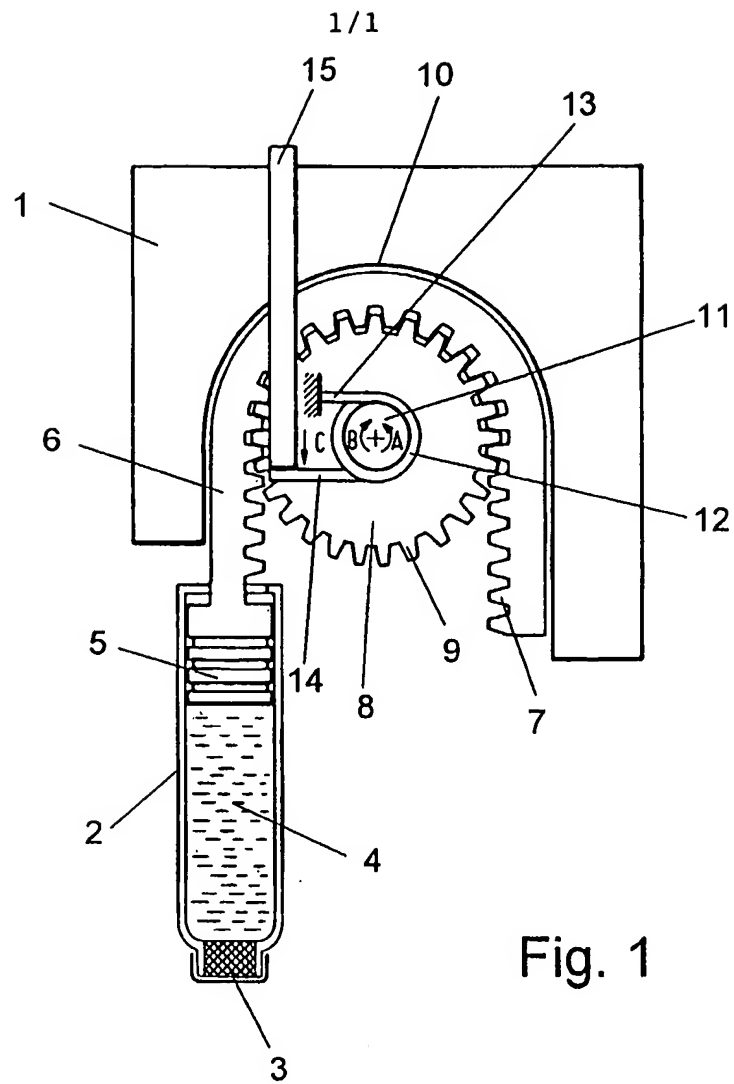
3. A drug delivery device according to claims 1 or 2, **characterised** in that the piston rod (6) is provided with a toothing (7) and is in engagement with a piston rod driving wheel (8) provided with a complementary toothing (9), said piston rod driving wheel (8) being mounted on said axle (11).

4. A drug delivery device according to claim 3, **characterised** in that the piston rod (6) is flexible and is positioned partly around the piston rod driving wheel (8).

5. A drug delivery device according to claim 4, characterised in that a guiding face (10) is provided in the housing (1), said flexible piston rod (6) being positioned between said guiding face (10) and said piston rod driving wheel (8).

6. A drug delivery device according to any one of claims 1-5, characterised in that the drug delivery device is provided with an exchangeable drug container (2).

7. A drug delivery device according to any one of claims 1-6, characterised in that the drug delivery device is an injection syringe.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 01/00259

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/315

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4367739 A (HARRY H. LEVEEN ET AL), 11 January 1983 (11.01.83), abstract, figure --	1-3
A	US 6003736 A (HENRIK LJUNGGREN), 21 December 1999 (21.12.99), abstract, figure --	1-3
A	US 3703941 A (KOICHI OHIEET AL), 28 November 1972 (28.11.72), abstract, figure --	1-3
A	WO 9509021 A1 (NOVO NORDISK A/S), 6 April 1995 (06.04.95), abstract, figure --	1-3

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

23 August 2001

Date of mailing of the international search report

24-08-2001

Name and mailing address of the ISA/

Swedish Patent Office

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 01/00259

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4820287 A (HENRY LEONARD), 11 April 1989 (11.04.89), abstract, figure --	1-3
A	WO 9810814 A1 (NOVO NORDISK A/S), 19 March 1998 (19.03.98), abstract, figure --	1-3
A	WO 9626754 A2 (SAMS, BERARD), 6 Sept 1996 (06.09.96), abstract, figure --	1-3
A	FR 2767479 A1 (LABORATOIRE AGUETTANT SOCIETE ANONYME), 26 February 1999 (26.02.99), abstract, figure --	1-3
A	US 5630339 A (THOMAS TUDAY), 20 May 1997 (20.05.97), abstract, figure -- -----	1-3

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/08/01

International application No.

PCT/DK 01/00259

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
US	4367739	A	11/01/83	EP	0076850 A	20/04/83
				JP	58500649 T	28/04/83
				WO	8203553 A	28/10/82

US	6003736	A	21/12/99	AU	733472 B	17/05/01
				AU	7757498 A	30/12/98
				BR	9809984 A	01/08/00
				CN	1259057 T	05/07/00
				EP	0988075 A	29/03/00
				NO	996025 A	08/02/00
				PL	337219 A	14/08/00
				WO	9856439 A	17/12/98
HU	0002581 A	28/11/00				

US	3703941	A	28/11/72	CA	944262 A	26/03/74
				DE	2101822 A,B,C	29/07/71
				FR	2077195 A,B	22/10/71
				GB	1295221 A	08/11/72
				JP	49017163 B	27/04/74

WO	9509021	A1	06/04/95	AU	7739494 A	18/04/95
				DK	109293 D	00/00/00
				EP	0721358 A	17/07/96
				JP	9502900 T	25/03/97
				PL	176898 B	31/08/99
				PL	313699 A	22/07/96
				RU	2142822 C	20/12/99
				US	5957889 A	28/09/99

US	4820287	A	11/04/89	CH	673226 A	28/02/90
				DE	3709871 A,C	23/12/87
				FR	2596278 A,B	02/10/87
				IT	1208343 B	12/06/89
				IT	8753157 V	18/03/87
				IT	8767214 D	00/00/00
				JP	62243552 A	24/10/87

WO	9810814	A1	19/03/98	AU	4199997 A	02/04/98
				EP	0927058 A	07/07/99
				JP	2001502196 T	20/02/01
				US	6110149 A	29/08/00

WO	9626754	A2	06/09/96	EP	0918555 A	02/06/99
				GB	9503969 D	00/00/00

FR	2767479	A1	26/02/99	NONE		

US	5630339	A	20/05/97	NONE		
